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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/359,975 | 07/23/99 | WEINER | UPAP-0345 |

HM22/0811

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| EXAMINER | |
|---|---|
| SANDALS,W | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | 8 |

**DATE MAILED:** 08/11/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/359,975 | Weiner et al. |
| **Examiner** | **Group Art Unit** |
| WILLIAM SANDALS | 1636 |

☒ Responsive to communication(s) filed on *May 12, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, and 115-147* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, and 115-147* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Response to Arguments*

1. Arguments set forth in Paper No. 7, filed May 12, 2000 with respect to the rejection of claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96 and 115-121 under 35 USC 112, first paragraph have been considered but are moot in view of the new ground(s) of rejection.

2. Amendments to claim 58 in Paper No. 7 have overcome the rejection under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96 and 115-147 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a pharmaceutical composition comprising DNA and a polynucleotide function enhancer and methods of immunization with the composition. While applicants have shown a composition comprising DNA and a polynucleotide function enhancer,

they have not demonstrated any pharmaceutical application for the composition comprising DNA and a polynucleotide function enhancer. In order to do so, undue experimentation is required. Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors. Many of these factors have been summarized in *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

The Wands factors as they apply to the instant claimed invention are as follows:

a- The quantity of experimentation necessary to reduce the instant claimed invention to practice would involve demonstration that a composition comprising DNA and a polynucleotide function enhancer provides an immune response. It is known that production of an immune response is dependent upon a particular antigenic presentation and appropriate adjuvant. The identity of a specific antigen and demonstration of the immunogenicity of the specific antigen is not predicatable, since each potential antigen must be tested to determine if it will elicit an immune response.

b- Only prophetic guidance and no examples are presented in the instant specification.

c- The nature of the invention is complex. The delivery of DNA to an animal for immunization and passive protection is a new and developing art as taught in Cho et al. at the abstract "[t]he factors essential for the successful development of this new claims of therapeutic agents are not necessarily the same as those for conventional small organic molecules" and at page 157, column 1 bottom, bridging to column 2, top "formidable transport and delivery problems are associated with macromolecular therapeutic agents. With all of these

disadvantages, one might wonder why investigators remain so interested in the prospectof using macromolecules as drugs. The answer lies in the potentially exquisite specificity that one can, at least theoretically, attain by using proteins or genes as therapeutic agents. The challenge is to convert the potentiality of macromolecular drugs into practical reality".

d- The prior art at the time of filing of the instant priority document Application No. 08/124,962, filed September 21, 1993, was teaching that it was unknown if DNA vaccines would be effective.

e- Those of skill in the art have taught the unpredictability of DNA vaccines. Rabinovich et al. taught at page 1401, column 3, "[t]he advent of recombinant DNA technology has stimulated the production and testing of new subunit vaccines designed to be safer and more efficient. Unfortunately, the limited immunogenicity of many of these candidates has hindered their development as potential vaccines. Strategies to enhance the immunogenicity of these candidate vaccines are therefore critical". Webster et al. taught at page 281 "[t]he ultimate vector for use in DNA immunisation in humans and other animals, that will meet all of the above requirements, is clearly desirable, but has not yet been perfected. Plasmids for use in DNA immunisation will continue to be refined in the coming years". Piscitelli et al. taught at page 68, column 2, bottom bridging to page 69, column 3, top, that those of skill in the art were still evaluating the use of DNA to produce an HIV immunization.

f- Therefore, given the analysis above, it must be considered that the skilled artisan would have needed to have practiced considerable non-routine, trial and error experimentation to enable the full scope of the claims.

***Conclusion***

5. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

William Sandals, Ph.D.
Examiner
August 10, 2000

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER